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10/524,252	03/07/2006	Reginald M Taylor	16218.013	4597

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
4173	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,252	TAYLOR ET AL.	
	Examiner	Art Unit	
	Paul W. Dickinson	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating topical diseases or conditions, does not reasonably provide enablement for prevention of topical diseases. Similarly, the term "prophylactic" in Claim 10 as a claim limitation lacks enablement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prevent topical diseases or conditions, commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to topical diseases. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the Examiner cites: http://health.yahoo.com/skinconditions-overview/cold-sores-topic-overview/healthwise--

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not

hw31979.html (accessed Nov 1, 2007). The reference teaches that the Herpes Simplex virus cannot be cured. Although treatment may lessen the duration of cold sores, the virus cannot be eliminated (see How are cold sores treated?).

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term "prevention", the examiner will adopt the broadest reasonable interpretation for same. Webster's Ninth New Collegiate Dictionary defines "prevention" as "to keep from happening or existing", i.e., to completely eradicate.

The claims are thus very broad insofar as they recite the "prevention" of topical diseases or conditions, i.e., the complete eradication of same. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live; recurrence is always a risk.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for prevention of topical diseases or conditions. No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing topical diseases or conditions, other than treating topical diseases or conditions. The latter is corroborated by the working examples.

"experimentation".

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent topical diseases or conditions as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

5. Suggested alternative language

Since the term "treating" is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active), the Examiner recommends deleting the term "preventing" and simply reciting "treatment" only instead.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4544761. '761 discloses a composition comprising a plurality of zinc glycerolate particles having a mean particle length of 10 microns (see Example 2). '761 further discloses the addition of a pharmaceutically acceptable carrier to the composition, including pharmaceutical carriers suitable for topical application of the composition to skin as a therapeutic substance (specifically, sunscreen) (see Examples 7 and 8). The latter example contains zinc glycerolate particles present in 32% by weight of the total composition (see Example 8). The composition disclosed by '761 is effective in the treatment of pruritus (itching), dermatitis (burns of the genital areas of babies which originate from ammonia liberated during the decomposition of urine-nappy rash), and psoriasis (see col 6, ln 3-15).

'761 further discloses a method for treating topical diseases or conditions, comprising topically administering to the skin a composition comprising a therapeutically effective amount of zinc glycerolate particles having a mean particle length of 10 microns (see Claims 1, 3, 6-8, 11, 14, 17-19; Example 2). The method is for treatment of humans (see col 1, ln 7-9).

There is no definition in the specification of what the Applicant means by "about" in the phrases "about 0.70 microns and about 1.0 microns", "about 0.60 microns and about 0.75 microns", "about 0.80 microns and about 1.1 microns", and "about 0.4 microns and about 0.6 microns" in Claims 1-4, respectively.

The Examiner finds it reasonable to interpret the phrase "a mean particle length of between about 0.70 microns and about 1.0 microns" in Claim 1 in one of two ways.

The first interpretation is a mean particle length between 0.70 microns and 1.0 microns. The second, and broadest reasonable interpretation, is any mean particle length that encompasses the instant functionality of the zinc glycerolate particles. The Examiner is using the latter interpretation, and the particles disclosed by '761 encompass the instant functionality of the zinc glycerolate particles as stated above. The same argument applies to the ranges "about 0.60 microns and about 0.75 microns", "about 0.80 microns and about 1.1 microns", and "about 0.4 microns and about 0.6 microns".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable by US 4544761 in view of US 20040026546 and US 20020022052.

As stated above, the Examiner finds it reasonable to interpret the phrase "a mean particle length of between about 0.70 microns and about 1.0 microns" in Claim 1 in one of two ways. The first interpretation is a mean particle length between 0.70 microns and 1.0 microns. The second, and broadest reasonable interpretation, is any mean particle length that encompasses the instant functionality of the zinc glycerolate particles. The Examiner is using the former interpretation here.

As stated above, '761 discloses a composition comprising a plurality of zinc glycerolate particles having a mean particle length of 10 microns. '761 further discloses the addition of a pharmaceutically acceptable carrier to the composition, including pharmaceutical carriers suitable for topical application of the composition to skin as a therapeutic substance, including a composition that is 32% by weight of the total composition. The composition disclosed by '761 is effective in the treatment of pruritus (itching), dermatitis (burns of the genital areas of babies which originate from ammonia

liberated during the decomposition of urine-nappy rash), and psoriasis. '761 further discloses a method for treating topical diseases or conditions, comprising topically administering to the skin a composition comprising a therapeutically effective amount of zinc glycerolate particles having a mean particle length of 10 microns. The method is for treatment of humans (see col 1, ln 7-9).

'761 fails to disclose zinc glycerolate particles with a mean particle length between the following ranges: 0.70 microns and 1.0 microns, 0.60 microns and 0.75 microns, 0.80 microns and 1.1 microns, and 0.4 microns and 0.6 microns. It is noted that '761 contemplates using zinc glycerolate particles with a mean particle length as low as 6 microns (see col 5, ln 46-51).

'546 teaches that it is known that the bioavailability of a particulate drug can be increased by decreasing its particle size (see ¶ 2).

'052 teaches a transdermal particulate composition wherein an improved delivery into mucosal epithelia of the bioactive agent occurred when the particles size was less than one micron (see abstract; ¶ 42). A preferred formulation comprising zinc glycerolate powder is contemplated (see ¶ 176).

In an effort to find zinc glycerolate particle formulations with improved bioavailability, one skilled in the art would be motivated to combine the disclosures of '761, '546 and '052, to afford the instant invention. Given the effectiveness of zinc glycerolate particles with a mean particle length of 10 microns disclosed by '761, it would be reasonable to decrease the particle size to increase the bioavailability of the

agent. Given the high bioavailability the bioactive agent in the transdermal particulate composition disclosed by '052, it would be reasonable to select ranges at or below one micron, with a reasonable expectation of success.

Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4544761 in view of US 20040026546, US 20020022052, WO 94/02131, and Apisariyakulm et al (Apisariyakulm et al, Zinc monoglycerolate is effective against oral herpetic sores, The Medical Journal of Australia, 1990, 152, p 54). As stated above, '761 discloses a method for treating topical diseases or conditions, comprising topically administering to the skin a composition comprising a therapeutically effective amount of zinc glycerolate particles having a mean particle length of 10 microns. '761 fails to disclose zinc glycerolate particles having a mean particle length in the range of 0.7 to 1.0 microns. '761 further fails to disclose a method for treating herpetic diseases, including fever blisters and cold sores.

As stated above, '546 teaches that it is known that the bioavailability of a particulate drug can be increased by decreasing its particle size.

As stated above, '052 teaches a transdermal particulate composition wherein an improved delivery into mucosal epithelia of the bioactive agent occurred when the particles size was less than one micron. A preferred formulation comprising zinc glycerolate powder is contemplated.

'131 teaches the effectiveness of topical administration of zinc glycerolate particles in treating herpetic diseases (see p 1, ln 3-4).

Apisariyakulm et al teaches the effectiveness of topical administration of zinc glycerolate particles in treating fever blisters and cold sores (oral herpetic sores) (see title).

In an effort to find improved treatments for herpetic diseases, including fever blisters and cold sores, one skilled in the art would be motivated to combine the disclosures of '761, '546, '052, '131, and Apisariyaklum et al, to afford the instant invention. As stated above, it would be reasonable to combine the disclosures of '761, '546, and '052 and make zinc glycerolate particles with improved bioavailability, wherein with mean particle length ranges are at or below one micron. Given the effectiveness of zinc glycerolate in the treatment of herpetic diseases, including fever blisters and cold sores, disclosed in '131 and Apisariyakulm et al, it would be reasonable to administer the zinc glycerolate composition topically to treat these conditions, with a reasonable expectation of success.

Conclusion

No claims is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson
Examiner
Art Unit 4173

November 1, 2007

11/6/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER